DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Food and Drug Administration
Rockville MD 20857

FEB 25 2000

WARNING LETTER

VIA FEDERAL EXPRESS

Mr. Reiner Thede
President
ERBE Elektromedizin, GmbH
Waldhoernlestrasse 17
72072 Tuebingen, Germany

Dear Mr. Thede:

During an inspection of your firm located in Tuebingen, Germany, on October 18-22, 1999, our investigator determined that your firm manufactures electrosurgical systems. Electrosurgical systems are devices as defined by section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above-stated inspection revealed that certain of these devices are adulterated under section 501(f)(1)(B) of the Act, in that they are class III devices under section 513(f) and do not have approved applications for premarket approval in effect pursuant to section 515(a) or approved applications for an investigational device exemption under 520(g).

Furthermore, the inspection revealed that those devices are misbranded under section 502(o) of the Act, in that the devices were not included in a list required by section 510(j) and notices or other information respecting the devices were not provided to the Food and Drug Administration (FDA) as required by section 510(k), and the devices have not been found to be substantially equivalent to predicate devices. Specifically, "Thermal devitalization of stenotic tumors in gastroenterology and bronchoscopy" is a new indication for use for the APC 300 Argon Plasma Coagulator that would need a new premarket notification [510(k)]. In addition, the new "Forced 4 Coagulation" for the ICC 300/350 electrosurgical generator appears to be a modification of technology that may change the performance of the device and, thus, would need a new premarket notification [510(k)].

Additionally, the above-stated inspection revealed that these devices are adulterated under 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the current good manufacturing practice (CGMP) requirements of the Quality System Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure of the document control procedures to include a complete documented history of both the changes and approvals, as required by 21 CFR 820.40(b). For example, several quality system procedures were revised without a documented history of changes, including the date and signature of management review and approval, specifically: Testing (QMH-1110), Purchasing Controls (QMH-1106), Process Controls and Production (QMH-1109), and Management Responsibility (QMH-1101).

2. Failure to establish and implement reaudits of deficient matters, as required by 21 CFR 820.22. For example, there is no written audit schedule for follow-up audits and no reaudit has been conducted after deficient areas were identified in the Production Department on November 4, 1998.

3. Failure to define responsibility for implementation of design activities and identify and describe the interfaces with other groups or activities in the design plan, as required by 21 CFR 820.30(b). For example, the design plan entitled "Zeitplanung" for the modified ICC-300/350 software version 4.0 does not define responsibility of implementation or identify and describe interfaces with appropriate groups or activities, given in the Pflichtenheft for ICC Version V4.00.

4. Failure to establish design input procedures that include a mechanism for addressing incomplete, ambiguous, or conflicting requirements, as required by 21 CFR 820.30(c). For example, the design input procedures entitled "Verfahrensanweisung" lacked requirements for addressing incomplete, ambiguous, or conflicting requirements (document VA-2204, version 001).

5. Failure of the design verification procedures to include or reference certain items needed and to resolve discrepancies in order to assure that design outputs meet design inputs, as required by 21 CFR 820.30(f). For example:

a. the combined design verification and validation document, "Inhaltsangabe," dated February 8, 1999, did not include or reference the following: (i) the test methods, (ii) acceptance criteria and tolerances for the maximum power output and peak voltage at no load, (iii) actual readings or theoretical calculations of the power output at each power setting above [redacted] watts when the pulse-modulated frequency starts changing, and (iv) actual readings of other high voltage measurements that would assure the Forced 4 Coagulation would reach a peak voltage of [redacted] volts at no load.

b. the design verification and validation document, "Inhaltsangabe," had ICC 300 and 350 actual test results of the maximum power output and peak voltage at a no load condition different from those listed in the operator's

manuals, neither set of values including tolerances, and no evaluation or resolution of the discrepancies.

6. Failure to document risk analysis performed as a part of design validation activities, as required by 21 CFR 820.30(g). For example, a hospital used a prototype ICC 300/350 unit with software version 4.0 but no formal risk analysis and evaluation of the new software version were compiled.

7. Failure to analyze and investigate component failures sufficiently to identify existing and potential causes of nonconforming product and identify corrective action(s), as required by 21 CFR 820.100(a)(1), (2), and (3). For example, trending data and monthly evaluations of significant failure rates of power modules, control boards, waveform generators, and sensor boards were not documented from January - October 1999 to detect shifts in quality of the PCB assemblies, determine root cause of the failures, and identify corrective action(s) that might be needed.

8. Failure to document the rationale for not conducting failure investigations and taking corrective action, as required by 21 CFR 820.100(b). For example, the evaluation report from 1998 indicated significant PCB failures but there was no trending data or monthly evaluation documented for the most recent 9 months.

9. Failure to conduct and document complete design validation activities, as required by 21 CFR 820.30(g). For example, the software validation for software version 4.0 used to control the modified ICC 300/350 may not have been conducted completely and results have not been formally documented.

10. Failure of the design control procedures to have the design transfer adequately reviewed to assure design specifications were correctly transferred to production specifications, as required by 21 CFR 820.30(h). For example, the design verification document does not define a specification range of the maximum power output for verification against production values.

11. Failure to establish adequate incoming inspection procedures, as required by 21 CFR 820.80(b). For example, the procedures established in April 1999 as corrective action to avoid acceptance of the incorrect size pressure reduction valves (PRV) did not specify inspection of the lip, thread sizes, or diameter, three critical characteristics identified in the complaint investigation.

12. Failure to include in design reviews an individual who does not have direct responsibility for design activities, as required by 21 CFR 820.30(e). For example, the design team identified in the project committee did not include an individual who does not have direct responsibility (document VA-2205, Version 003).

This letter is not intended to be an all-inclusive list of deficiencies. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA 483 issued at the close of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance programs. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systemic problems you must promptly initiate permanent corrective actions.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts.

Given the serious nature of the problems noted above, all medical devices manufactured by ERBE Elektromedizin GmbH may be detained upon entry into the United States without physical examination until these violations are corrected. In order to prevent the devices from being subject to detention, you will need to: (1) provide the necessary premarket notification information to the Office of Device Evaluation for their review and clearance, and (2) provide a written response to the charges in this Warning Letter for our review.

After we notify you that the responses are adequate, a re-inspection of your facility will be required to verify that your corrective actions have been implemented. As soon as the inspection has taken place, the implementation of your corrections verified, and your new 510(k) notifications have been cleared, your devices may resume entry into this country.

Please notify this office in writing of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. Please include any and all documentation to show that adequate corrections have been achieved. In the case of future corrections, an estimated date of completion and documentation showing plans for correction should be included with your response to this letter.

If documentation is not in English, please provide a translation to facilitate our review.

Please submit your response to: Director, Division of Enforcement I (HFZ-323), Office of Compliance, Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Maryland, 20850 USA. If you have any questions, please contact Ms. Cory Tylka of the General Surgery Devices Branch at (301) 594-4595, ext. 170 or FAX: (301) 594-4636.

Sincerely yours,

Lillian J. Gill
Director
Office of Compliance
Center for Devices and
Radiological Health

CC: Mr. Christian Erbe
President
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